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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,592	10/02/2003	John M. Adams	1900-3-5	8226

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EXAMINER	
DOWE, KATHERINE MARIE	

ART UNIT	PAPER NUMBER
3734	

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Please find below and/or attached an Office communication concerning this application or proceeding.

NT

Office Action Summary	**Application No.** 10/677,592	**Applicant(s)** ADAMS ET AL.	
	Examiner Katherine M. Dowe	**Art Unit** 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) *1-30,38,41-44,46-50,56 and 62-65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-37,39,40,45,51-55 and 57-61* is/are rejected.

7)☒ Claim(s) *31-37,39,40,45,51-55 and 57-61* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 October 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date *10/02/2003*.

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Priority

1. This application discloses and claims only subject matter disclosed in prior Application No.09/956,623, filed September 19, 2001, and names an inventor or inventors named in the prior application. Accordingly, this application may constitute a continuation or division. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the feature of the reinforcement overlying the outer wall of a vein (claims 32 and 39) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

2. Claim 31 is objected to because of the following informalities: The last phrase "overlying the wall of the vein with the reinforcement structure" repeats the first phrase "a reinforcement structure arranged to continuously overlie… a wall of a vein". Please delete the last phrase. Appropriate correction is required.

3. Claims 31-37, 39-40, 45, 51-55, and 57-61 are objected to because of the following informalities: Claims 31-37 refer to a "reinforcement structure" while claims 39-40 and 45 refer to a "reinforcement device" and claims 51-55 and 57-61 refer to a "vascular reinforcement device". Please choose one term to be consistent. Appropriate correction is required.

4. Claim 53 is objected to because of the following informalities: "with" should be "within" in the following sentence – "..the step of guiding the vascular reinforcement device into position with the left renal vein through a catheter". Appropriate correction is required.

5. Claim 54 is objected to because of the following informalities: "the vein" should be "the *left renal* vein" to maintain correct antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 31 and 33-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Stack et al. (US 5,527,337). Regarding claim 31, Stack et al. disclose a reinforcement structure, or stent, for disposition within a blood vessel designed with sufficient hoop strength to support the vessel wall against collapse along with a method of use (col 2, lines 29-31; Fig 4). Since the vessel, including veins, remains open, the method of Stack et al. is capable of reducing increased vascular pressure in a vein in the presence of forces applied external to the vein. Stack et al. disclose the steps of providing a reinforcement structure with a longitudinal dimension and a cross-sectional dimension (Fig 4) arranged to continuously overlie, in adjacent relation to, a wall of the vein (col 5, lines 43-44). Furthermore, Stack et al. disclose the reinforcement structure is longitudinally flexible (col 2, line 65), and is resistant to cross-sectional area change (col 4, lines 65-67).

Regarding claim 33, Stack et al. disclose the step of overlying the inner wall of the vein with the reinforcement structure (col 5, lines 43-44; Fig 4).

Regarding claim 34, Stack et al. disclose the step of guiding the reinforcement structure into position within the vein through a catheter (col 3, lines 17-21).

Regarding claim 35, Stack et al. disclose the step of positioning the reinforcement structure while it is in a collapsed state and thereafter expanding the reinforcement structure to a deployed state (col 3, lines 4-8).

Regarding claim 36, Stack et al. disclose the step of expanding the reinforcement structure with a balloon (col 3, line 26-29; col 5, lines 59-65).

Regarding claim 37, Stack et al. disclose the step of feeding a catheter until the distal end of the catheter is at a desired position within the vein and thereafter, advancing the reinforcement structure through the catheter to the desired position (col 5, lines 17-34).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 40, 45, and 57-61 rejected under 35 U.S.C. 103(a) as being unpatentable over Stack et al. (US 5,527,337) as applied to claims 31 and 33-37 above, and further in view of Park et al. (Nutcracker syndrome: intravascular stenting approach). Regarding claims 40 and 58-61, Stack et al. disclose the invention substantially as claimed for reducing increased vascular pressure in a vein. However, Stack et al. do not disclose the device could be used specifically in a renal vein or even more specifically, the left renal vein. Park et al. disclose the clinical syndrome caused by the impingement of the left renal vein between the superior mesenteric artery and the abdominal aorta may be treated with an intravascular stent (pg 99, col 1), such as the device disclosed by Stack et al. Park et al. disclose a stent was inserted over a catheter into the left renal vein to relieve the compression (pg 100, col 1). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Stack et al. such that the reinforcement device could be placed in a renal vein, or more specifically, the left renal vein.

Regarding claim 45, Park et al. further disclose the left renal vein narrows between the aorta and the superior mesenteric artery and the abdominal aorta, but alternatively the distal portion of the left renal vein widens (page 101, col 1). While Park et al. do not explicitly state the stent was placed in the left renal vein in a position overlying the aorta, it would have been obvious to one having ordinary skill in the art to position the reinforcement device within the left renal vein such that it supports the portion of the vein that is narrowing due to the clinical syndrome. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Stack et al. such that the reinforcement device could be placed in the portion of the left renal vein that crosses the aorta.

Regarding claim 57, Park et al. disclose hypertension is a possible cause of the superior mesenteric artery and the abdominal aorta impinging the left renal vein (pg 99, col 1). Thus, one method of treating hypertension is to reduce the increased vascular pressure on the left renal vein with a reinforcing device, as previously discussed. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Stack et al. such that the reinforcement device could be placed in the portion of the left renal vein that crosses the aorta to treat hypertension.

11. Claims 51-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al. (Nutcracker syndrome: intravascular stenting approach) in view of Stack et al. (US 5,527,337) and further in view of Tokunaga et al. (Dilation of the Left Renal Vein in Preeclampsia). Regarding claims 51 and 52, Park et al. disclose an impingement of the left renal vein between the superior mesenteric artery and the abdominal aorta, which may cause hypertension, may be treated with an intravascular stent (pg 99, col 1) wherein the stent is inserted over a catheter into the left renal vein to relieve the compression (pg 100, col 1). Park et al. further disclose the left renal vein narrows

between the aorta and the superior mesenteric artery and the abdominal aorta, but alternatively the distal portion of the left renal vein widens (page 101, col 1). While Park et al. do not explicitly state the stent was placed in the left renal vein in a position overlying the aorta, it would have been obvious to one having ordinary skill in the art to position the reinforcing device within the left renal vein such that it supports the portion of the vein that is narrowing due to the clinical syndrome.

However, Park et al. do not disclose preeclampsia is caused by hypertension. Tokunaga et al. disclose preeclamptive women have a relative constriction of the left renal vein where it crosses the abdominal aorta compared to normotensive pregnant women (page 358, col 2). Thus, one method of treating preeclampsia is to reduce the increased vascular pressure on the left renal vein with a reinforcing device, as previously discussed by Park et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Park et al. such that the method of providing a reinforcement device to be placed in the left renal vein overlying the aorta is additionally used to treat preeclampsia.

Furthermore, regarding claims 53-55, Park et al. do not disclose the methods of implanting the reinforcement device. Stack et al. disclose a similar method of providing a reinforcement device for a vein, including the steps of guiding the reinforcement device into position within a vein through a catheter (col 3, lines 17-21), positioning the reinforcement device while it is in a collapsed state and thereafter expanding the reinforcement device to a deployed state (col 3, lines 4-8), and expanding the reinforcement device with a balloon. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Park et al. such that the method of providing a reinforcement device to be placed in the left renal vein overlying the aorta includes the specific steps of how one may insert the device.

12. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stack et al. (US 5,527,337) in view of Ferrazzi (US 2003/0158570 A1), and further in view of Alferness (US 6,165,122). Stack et al. disclose the invention substantially as claimed for providing a reinforcement structure to reduce increased vascular pressure in a vein. However, Stack et al. do not disclose the step of positioning the reinforcement structure such that it overlies the outer wall of a vein. Ferrazzi discloses a device and method for reinforcing a cardiac wall to treat heart failure. The device (Fig 1, elements 6-8) is inserted on the endocardium of the ventricular cavity (1), or the inner wall of the heart (paragraph 0068). However, Alferness discloses an alternate method for reinforcing a cardiac wall (col 1, line 11) wherein the cardiac reinforcement structure is applied to the epicardial surface, or the outer walls, of the heart (col 1, lines 19-20; col 2, lines 62-63; Fig 5). Both methods aim to treat heart failure by reducing ventricular volume and optimizing ventricular wall shape to maximize diastolic and systolic activity of the heart, although one is placed on the interior of the heart while the other is placed on the exterior of the heart. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Stack et al. such

that the reinforcement structure may be placed in a position that overlies the outer wall of a vein, in addition to the alternate position of overlying the inner wall of a vein.

13. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stack et al. (US 5,527,337) in view of Ferrazzi (US 2003/0158570 A1) and of Alferness (US 6,165,122) as applied to claim 32 above, and further in view of Park et al. (Nutcracker syndrome: intravascular stenting approach). Stack et al. disclose the invention substantially as claimed for providing a reinforcement structure to reduce increased vascular pressure in a vein. However, Stack et al. do not disclose the step of positioning the reinforcement structure such that it overlies the outer wall of a vein. Alferness and Ferrazzi show that is obvious to position a reinforcement structure on the inner wall of a vessel or the outer wall of a vessel. However, no party discloses the reinforcement structure should be inserted in a renal vein. Park et al. disclose an impingement of the left renal vein between the superior mesenteric artery and the abdominal aorta, which may cause hypertension, may be treated with an intravascular stent (pg 99, col 1) wherein the stent is inserted over a catheter into the left renal vein to relieve the compression (pg 100, col 1). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Stack et al. such that the reinforcement structure may be placed in a position that overlies the outer wall of a vessel, in addition to the alternate position of overlying the inner wall of a vessel, wherein the vessel is specifically a renal vein.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5,617,878	Taheri	US 5,441,515	Khosravi et al.
US 5,064,435	Porter	US 5,366,504	Anderson et al.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine M. Dowe whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Hayes can be reached on (571)272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

kmd

MJ Hayes

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER